UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,710	07/27/2005	Kamel Khalili	06056-0309US1	4632

23973 7590 03/19/2008

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,710	KHALILI, KAMEL	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 18-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 2/11/08 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-12 and 18-25 are pending.

The objection to the specification is withdrawn in view of applicant's amendment.

The objection to the claims is withdrawn in view of applicant's amendment.

The rejection of claim 27 under 35 U.S.C. 112, first paragraph, is withdrawn in view of its cancellation.

All art rejections are withdrawn in view of the cancellation of claims 26 and 27.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8, 12, 18-19 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Please note that Part B is withdrawn. The reasons for this rejection are of record in the paper mailed 8/17/07.

This rejection is maintained in view of the terminology "one or more agnoproteins" in claims 1 and 12.

Applicant argues that over 100 JVC agnoproteins are known and that the specification provides a consensus sequence and that experimental evidence shows the specific regions required for functional activity. First of all, the terminology "agnoproteins" as discussed in the previous action reads on protein having at least 50% identity to SEQ Id NO. 1. While there may be over 100 known, there is no objective evidence to show that these have at least 50% identity to SEQ Id No. 1. Second, the terminology "agnoproteins" as claimed in claims the rejected claims does not specify the core sequence. Third, there is no functional activity recited for the terminology "agnoprotein" in the rejected claims.

Claims 1-12 and 18-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The reasons for this rejection are of record in the paper mailed 8/17/07.

Applicant argues that the in vitro data is acceptable if determined from the perspective of one skilled in the art and cites MPEP 2164.02. The section cited by applicant clearly states "if the art is such that **particular model is recognized as correlating to a specific condition**" (emphasis added). As stated in the rejection, those skilled in the art do not readily recognize in vitro data as correlatable to in vivo use. Thus, the perspective of those skilled in art shows that in vitro data is not correlatable to in vivo use and applicant has only provided in vitro data. With respect to the particular model as being correlatable to a specific condition, applicant had not provided any model. Applicant seems to think that the human U87MG glioblastoma cell line is such a model. Applicant states that Zhao et al and Yoshida et al shows that those skilled in the art recognize that this in vitro model correlated to in vivo. First of all, there reference were not attached. Second, in response to those section cited by applicant, these reference indicate that the in vitro data indicates a **potential** usefulness in in vivo treatment and that the drug **may be considered** to in vivo testing on animals. Thus, those skilled in the art clearly recognize that in while in vitro data is a precursor to in vivo testing, it does not mean that the drug will be effective in vivo (absent in vivo data).

Applicant further argues that the Office has no authority to require clinical trails. The Examiner is NOT requiring clinical trials--the rejection is based on the lack of the in vitro data to be correlated to in vivo use (the in vivo use does not have to clinical trials)--ie the unpredictabilitiy in the art. Applicant further cites *In Re Brana* 51, F.3d 1560,1568. The facts in the *In Re Brana* case are distinguished from the facts in the instant application. First, the claims in the case were directed to compounds and their use in vivo. Applicant's claims are method claims which require an in vivo use. Second, the cell lines used in the case were recognized by NCI as being correlatable to in vivo use. There is no objective evidence of record to show that the U87MG glioblastoma cell line used by applicant, Zhao et al and Yoshida et al can be correlated to in vivo use.

Claims 12 and 18-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Please note that item "a" is withdrawn. The reasons for this rejection are of record in the paper mailed 8/17/07.

Applicant argues that term "derivatized" is clear in light of page 19 of the specification. Page 19 does not define this term. Does applicant mean that the cells were --obtained-- from the glioblastoma cell line??

New Grounds of Rejection

Claims 1-12 and 18-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

In claims 1 and 12, section "(ii)" the terminology "wherein said one or more fragments comprise amino acid residues 1-36 of SEQ ID NO:1" is new matter. The only reference to such a fragment in on page 37, lines 5-11. This section states refers to the use of GST-Agno 1-36 in a pull down assay. This does not the above wherein clause and the use of the fragment in the claimed method because (1) the GST-Agno 1-36 is not SEQ ID NO. 1 and (2) the pull down assay is not an method of inhibiting cell growth, it is merely an analytical tool.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

//Sheela J Huff//

Primary Examiner, Art Unit 1643